premio 30 laser duo

User manual

Keep with your instrument

English

Sedatelec®

YOUR WAY OF CARE,
OUR QUALITY DEVICES

Thank you for choosing the Premio 30 laser duo!

Since it was formed, Sedatelec has based its work on studies carried out in complementary medicine, particularly those conducted by Dr P. Nogier, the father of auriculotherapy and auriculomedecine, to offer practitioners novel, highly reliable, high performance instruments.

Nowadays we are developing and incorporating the values of respecting patient, practitioner and the environment into our products, consistent with the highest level medical standards, so that you can practice comfortably and effectively.

We are pleased to work with our excellent permanent research partners and are also proud of our increasing participation in sharing medical information between the different people who work in the field. Please do not hesitate to contact us for any further information by email at infomed@sedatelec.com.

I hope you will be fully satisfied with your use of Premio 30 laser Duo. I am happy to hear from you and am open to any ideas to advance your practice in this novel medical approach.

Best wishes,

Thierry Garaboux, Chairman.

TABLE OF CONTENTS

SAFETY INSTRUCTIONS, RESIDUAL RISKS AND PRECAUTIONS FOR USE 4
INDICATIONS & CONTRAINDICATIONS 7
DESCRIPTION OF THE PREMIO 30 LASER DUO 9
HOW TO USE THE PREMIO 30 LASER DUO.....11
TECHNICAL SPECIFICATIONS.....14
FREQUENCIES & PROGRAMMES.....15
MAINTENANCE.....15
TROUBLESHOOTING - RECYCLING 16
APPENDIX 1: REGULATORY AND STANDARD RELATED INFORMATION.....17
APPENDIX 2: PERIODICAL TECHNICAL SECURITY CHECKS 19
APPENDIX 3: ELECTROMAGNETIC COMPATIBILITY.....20
APPENDIX 4: INSTRUMENT BOOKLET.....25

SAFETY INSTRUCTIONS, RESIDUAL RISKS AND PRECAUTIONS FOR USE

The **Premio 30 laser duo** is an infrared laser which emits a laser beam at a rate of 905 nm.
The Maximum Permitted Emissions (MPE) are 0.269 J/m^2 for the skin and $2.47*10^{-4}$ J/m^2 for the cornea.
The "Laser danger" symbol, placed on the end of your device, represents the "opening indicator plate" designating an **"opening for laser radiation"**

Safety for the skin
The laser emission from the Premio 30 laser duo is under this MPE and the beam can be directed onto the skin entirely safely without causing harm.

Safety for the eyes
Important note: The instrument must **never be used to treat the globe of the eye**.
The Nominal Ocular Danger Distance (NODD) is the distance from which the light applied to the eye must be less than the MPE for the cornea.
The NODD for the Premio 30 laser duo is 50 cm.
Whenever the laser is handled less than 50 cm from the eyes, it is therefore recommended that anyone who could accidentally look at the laser beam wears the protective glasses intended for this purpose.

Precautions for use of the Premio 30 laser duo

You are recommended:

- Not charge it in stormy weather,
- Not to use it in an environment containing by electromagnetic emissions outside of standard levels (eg: close to a CT scanner or MRI),
- Not to use it if the casing is not intact,
- Not to use it in an explosive environment,
- Not to subject it to ionising irradiation (eg: X-rays),
- Not to store it at temperatures of under -20°C or over 50°C,
- Never to immerse it in a liquid.

The Premio 30 laser duo contains a Li-Ion technology battery which must only be replaced by the staff instructed by Sedatelec.

It is essential that only the charger designed for the **Premio 30 laser duo** is used. Use of any other charging system could damage the instrument and may cause a high **electrical discharge** for the user or a **risk of explosion**. **The charger must remain accessible to be disconnected from the power supply.**

For safety reasons, the instrument is provided with a **laser key**, which can restrict its use to authorised personnel.

The Premio 30 laser duo requires **technical safety checks** at least every **24 months**. These must be carried out by people who have knowledge, equipment and experience to carry out these checks (cf. appendix 2).

☞ The Sedatelec technical department carries out all of the appropriate technical tests on the Premio 30 laser duo.
Contact us…

Where applicable, Premio 30 laser duo should be installed and used in accordance with the standard CAN/CSA-Z386-14: Safe Use of Lasers in Health Care Facilities

Indications

The **Premio 30 laser duo** is used for laser biostimulation (coherent light) or locally on painful pathological areas of the body.

The indications are those recognized for acupuncture, Ear Acupuncture.
Its use requires **skilled staff** who have sufficient knowledge of the indications, contraindications and medical risks of laser biostimulation, in a medical situation.

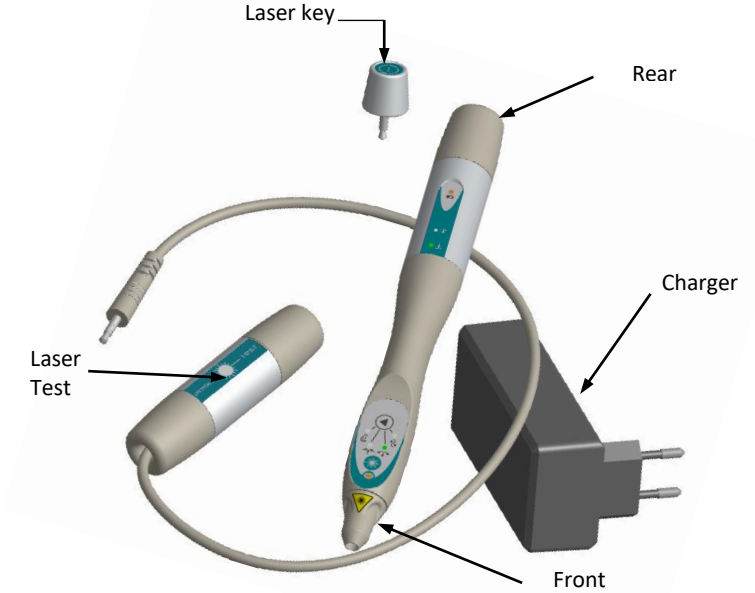
Contraindications

- Direct contact with mucosal membranes or broken skin.
- Treatment of endocrine areas (particularly in children).
- Treatment of the globe of the eye.
- Treatment of abdomen in pregnant women.
- Treatment of the chest region in a patient with a cardiac pacemaker.
- Exposure to sunlight or artificial UV light for 3 to 4 weeks before treatment.
- Hypersensitivity to light at 905 nm.
- Previous use of anticoagulants and aspirin.
- Receipt of medicines when exposure to sunlight is contraindicated.
- Receipt of oral isotretinoin medicines or anticoagulants.
- Past history of cheloid or hypertrophic scarring.
- Active infection/compromised immune system.
- Past history of herpes.

DESCRIPTION OF THE PREMIO 30 LASER DUO

The **Premio 30 laser duo** is supplied in a bag containing:

- A handpiece Premio 30 laser duo,
- A specific laser key,
- A test laser box,
- A battery charger,
- A pair of protective glasses with its manual,
- An instruction for use manual.



General description of the Premio 30 laser duo

Front panel

Laser beam output: invisible laser radiation

"Laser Danger" and "laser aperture" indicator

Laser emission indicator

Laser emission operating key

Laser stimulation programme indicator:

	Harmonisation	Acupuncture
	Dispersion	
	Tonification	
	Nogier frequencies scanning*	Ear Acupuncture

Type of laser stimulation selection key

Rear panel

Superficial penetration indicator

Deep penetration indicator

Battery charge indicator

Laser key

ON/OFF key and selection key for penetration depth

**The application of Nogier frequencies with this device has not been authorised by Health Canada for lack of sufficient clinical studies*

HOW TO USE THE PREMIO 30 LASER DUO

Use of commands or settings or carrying out procedures other than those described in this manual may result in exposure to dangerous irradiation.

Before starting

a. To recharge the **Premio 30 laser duo:**

The **Premio 30 laser duo** cannot be used during charging.

- Remove the laser key,
- Insert the charger plug into the instrument,
- Connect the charger to the power supply.

Power indicator: (extract from the documentation *)

- **Yellow: Charging** (steady then flashing at the end of charging)
- **Solid Green: Fully charged the battery.**
- **Flashing green:** The PREMIO is not connected.

See charger manual * for:

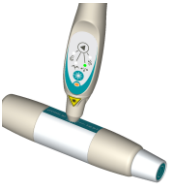
- LED off or blinking red: Battery / charger fault
- Solid yellow + Flashing red: Temperature fault

*: See the attached manufacturer's manual or on https://www.mascot.no/downloads/user-manuals/battery-chargers/ “chargers_li-ion”)

In the event of a **Battery fault**: See chapter Troubleshooting.

b. To check correct operation of the **Premio 30 laser duo:**

- Remove the laser key,
- Introduce the test laser plug into the instrument,
- Connect the laser key to the test laser,
- Press on the key.



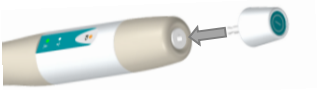
- Press on the emission key => continuous audible signal (if no signal, contact your distributor or Sedatelec),
- Apply the laser beam contact with the test laser unit.

If the audible signal remains unchanged, this means that the energy emitted is not within the -20%/+20% of nominal value band. You should then contact your distributor or Sedatelec to have your instrument adjusted.

Note: After using, disconnect the **Premio 30 laser duo** test laser in order that the battery does not discharge.

Starting and operating information

a. **Insert the key** into its socket on the back of the instrument. Press on the ON/OFF key .



b. **Checking the battery charge indicator:**

- Slow flashing: recharge recommended
- Fast flashing: the instrument may stop at any time; the battery is in urgent need of recharging.

Important comment: when switched on, the **Premio 30 laser duo** returns to the configuration for the stimulation mode in last use, in superficial penetration.

c. Select the stimulation mode: press on the key to select the desired programme: harmonisation, dispersion, tonification or Nogier frequency* scanning.

d. In Acupuncture positions, to select the treatment depth press on the key to alternatively select laser penetration depth for superficial or deep points.

Note: In the Ear Acupuncture position, depth is selected automatically.

e. Press on the key**:** the light indicator and a continuous audible signal inform the user that the laser is being emitted. After 30 seconds, a beep is emitted and the laser emission is automatically stopped.

f. To stop the beam being emitted during the cycle of 30 seconds, press on the key again.

Stopping the instrument

a. Long press on the key.

Note: The instrument also stops automatically after 2 minutes without use.

b. Remove the key.

**The application of Nogier frequencies with this device has not been authorised by Health Canada for lack of sufficient clinical studies*

TECHNICAL SPECIFICATIONS

Manufacturer	**Sedatelec**
Name of the device	**Premio 30 laser duo**
Type	Infrared laser

Emission features

Type of laser diode	InGaAs/GaAs
Wavelength	905 nm
Crest power	16.1 / 43.7 W (typical, not tested)
Energy per pulse	1.125 / 3.6 µJ
Energy per 30 sec	15 / 50 mJ
Emission frequency	100 – 10000 Hz 73 – 4672 Hz
Beam divergence	9° x 25°

Electrical supply

Internal battery	Li-Ion 3.6V 850 mAh
Li-Ion charger	90-264V ~/ 47-63Hz

Mechanics

Handpiece	213mm x 25mm
Weight of handpiece	111g

Operating conditions

Temperature	between 10°C and 35°C
Relative humidity	< 70 %
Atmospheric pressure	between 70 kPa and 106 kPa

Storage and transport

Temperature	between -20° and 50°C
Relative humidity	< 90 %
Atmospheric pressure	between 70 kPa and 106 kPa

Eye protection

Required optical density	>=2
Energy/pulse lighting	$8.2*10^{-3}$ J/ m^2 to 10cm

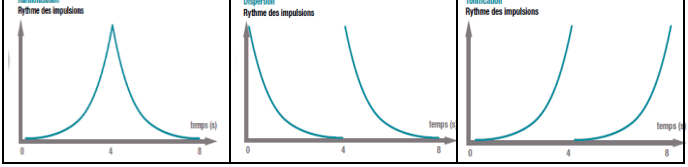
MANUFACTURED IN FRANCE

FREQUENCIES & PROGRAMMES

	Harmonization	Acupuncture
	Dispersion	
	Tonification	
	Nogier frequencies scanning* from A to G (73 to 4672 Hz)	Auricular acupuncture

Form of stimulation :

Harmonization	Dispersion	Tonification
100Hz à 10kHz et 10kHz à 100Hz	10kHz à 100Hz	100 à 10kHz



MAINTENANCE

We recommend routine disinfection of parts which may come into contact with patients.

Your **Premio 30 laser duo** does not require specific maintenance and can be cleaned with a cloth soaked in soapy water, 70°C alcohol or with a cold disinfectant.

Note: The instrument is not watertight and must **not be sprayed or immersed** in a fluid.

When **not used for long periods of time**, it is recommended that the instrument is stored with the battery charged and

that at least 1 charge/discharge cycle is carried out every 6 months.

The **laser protective glasses** can be cleaned with a soft cloth soaked in soapy water.
If the lenses are perforated, scratched, damaged or change in colour, or if the frame is damaged, the protective glasses must no longer be used and must be replaced.

You must not attempt to change or repair the parts inside the instrument or its accessories.

Any such attempt will invalidate the guarantee and may cause serious risks to yourself, those around you and your patients.

TROUBLESHOOTING - RECYCLING

If the instrument does not function correctly, return it completely in its original bag to your retailer or to Sedatelec with your comments.

When disposing of your Premio 30 laser duo, note that it contains electronic components and you should observe the current instructions for your country.

APPENDIX 1: REGULATORY AND STANDARD RELATED INFORMATION

Classification:

The Premio 30 laser duo is a class IIa medical device according to directives 93 /42 EEC and 2007/47/EC.

Applicable standards:

- **NF EN ISO 14971 :2013**
- **EN 60601-1: 2012**
- **IEC 60601-1-2 :2014**
- **IEC 60601-2-22 : 2012**
- **IEC 60825-1 :2014**
- **NF EN1041 :2008**.
- **ISO 15223-1 :2017**

SYMBOLS USED

Sedatelec	**Manufacturer**
	"Refer to the manual / instruction booklet"
	Dispose with **electrical waste** (directive DEEE)
CE 0123	**EC Mark** ensuring compliance with directives 93/42/EEC and 2007/47/EC awarded by **TÜV SÜD Product Service**. The notified body, registration number 0123.

Maximum and minimum limits of :

Atmospheric pressure | Hygrometry | Temperature

LABELS USED

Positioning: *on the device* : :

SN Serial number of the device
Battery: Li-ion 3.6V 0.85Ah
Charger: DC 4.2V 0.6A

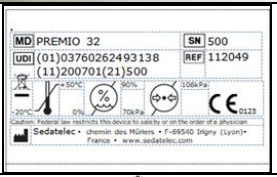
Positioning:: *On food*

Product designation
QR code + digits: UDI identifier *

REF : Device reference

: Name and address of manufacturer

: Date of manufacture



Positioning: *On the box*

UDI: UDI identifier *

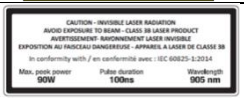
MD : Medical Device

Positioning: *Towards the laser output of the device*

Laser danger (+ indication by the tip of the warning "laser opening")

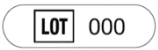
Positioning: *In this manual*

Warning: "laser opening"
Laser radiation is emitted by the diode located at the end of the tip



Positionnement : *in the case*

Warning: "invisible laser radiation. Dangerous beam exposure. Class 3B laser device according to IEC 60825-1.



Positioning: *On the "laser test" box*

LOT : batch number of the "laser test"

* UDI: Unique identifier of the product

APPENDIX 2: PERIODICAL TECHNICAL SECURITY CHECKS

Reminder: This laser device must have technical safety checks **every 24 months.**

Visual examination:

- Of the overall device,
- Of the labelling: identification and warning labels, commands and control markings, current method of use etc.

Operating control depending on method of use:

- Starting,
- Setting commands and indicators,
- Confirming the frequencies emitted,
- Checking timer.

Checking emitted energy:

- Check crest power emitted by each pulse

Technical safety check:

- Laser Test check
- Examination of the laser safety key

We would thoroughly recommend that you perform these checks.

☞ ***Sedatelec is at your service to do these!***

APPENDIX 3: ELECTROMAGNETIC COMPATIBILITY

Appropriate electromagnetic environment.
The Premio 32D laser is suitable for use in all facilities including domestic and those directly connected to a low voltage public electrical supply network and domestic building supplies.
The Premio 32D laser uses RF energy only for its internal operation. As a result its RF emissions are therefore very low and are not liable to cause interference with a neighbouring electrical instrument.

WARNING: Avoid using this instrument next to other machines as it may cause incorrect operation. If use is required, this and other instrument should be monitored to confirm their correct operation.

Emissions and immunity test according to IEC 60601-1-2:

Emissions tests	Compliance	Comments
Emission of conducted disturbance	YES	CISPR 11 Class B, Group 1
Emission of irradiation disturbance	YES	CISPR 11 Class B, Group 1
Emission of harmonics	NA	Power less than 75W
Emission of voltage/clashing fluctuations	NA	Test not required as the instrument does not produce significant voltages

Manufacturer's recommendation and statement – electromagnetic immunity			
The **Premio 30 laser Duo** is designed for use in the electromagnetic environment specified below. The client or user of the **Premio 30 laser Duo** should ensure it is used in such an environment.			
Test of immunity	**Compliance with IEC 60601**	**Level of compliance**	**Electromagnetic environment - recommendation**
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV on contact ± 15 kV in air	± 8 kV on contact ± 15 kV in air Direct pressure on the keys can stop the laser emission.	Floors should be wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30 %.
Rapid transitory bursts IEC 61000-4-4	± 2 kV for power supply cables ± 1 kV for input/ output cables	± 2 kV for power supply cables Not applicable	The quality of the power supply must be identical to a commercial or hospital environment.
Transitory power surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV normal mode	± 1 kV differential mode Not applicable	The quality of the power supply must be identical to a commercial or hospital environment.

Test of immunity	Compliance with IEC 60601	Level of compliance	Electromagnetic environment - recommendation
Voltage drop, power cut and power variations IEC 61000-4-11	< 5% U_T (>95% drop of U_T) for 0.5 cycle 40% U_T (60% drop of U_T) for 5 cycles 70% U_T (30% drop of U_T) for 25 cycles <5% U_T (95% drop of U_T) for 5 sec.	< 5% U_T (>95% drop of U_T) for 0.5 cycle 40% U_T (60% drop of U_T) for 5 cycles 70% U_T (30% drop of U_T) for 25 cycles The appliance stops then restarts when powering back up	The quality of the power supply must be identical to a commercial or hospital environment. As the instrument is battery-operated, only charging is impacted by the quality of the electrical supply.
Network frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	The quality of the magnetic field at the frequency of the electricity network must be identical to a commercial or hospital environment.
NOTE U_T is the alternating network voltage before application during trials			

Test of immunity	Compliance with IEC 60601	Level of compliance	Electromagnetic environment - recommendation
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz Discrete 9, 27 or 28 V/m frequencies	3 Veff 3 V/m Discrete 9, 27 or 28 V/m frequencies	WARNING: RF portable communication devices should not be used (including peripherals such as aerial cables and external aerials) closer than 30 cm (12 inches) from any part of the Premio 30 laser duo, including the cables, otherwise the performance of these instruments may be reduced.

APPENDIX 4: INSTRUMENT BOOKLET

Type of instrument: **Premio 30 laser duo**

Serial number:

Manufacturer: **Sedatelec**
Chemin des Mûriers
F-69540 IRIGNY

Distributor:

Acquisition date:

VISUAL EXAMINATION

Date	Performed by	Comments

OPERATING CHECK

Date	Performed by	Comments

ENERGY EMISSION CHECK

Date	Performed by	Results	Comments

TECHNICAL SAFETY CHECK

Date	Performed by	Comments

Acupuncture becomes simple and painless

Device dedicated to stimulation of acupuncture and Ear Acupuncture points by an infrared laser ray, the **Premio 30 laser duo** guarantees you the results of traditional practice.

It frees you from all the restrictions and unpleasant aspects of punctures, inspires confidence to your patient and offers you comfortable working and entirely safe mastering of the therapeutic procedure.

For effective, comfortable, safe, everyday practice.

Your distributor:

Last revision: Nov 2020

Sedatelec®
YOUR WAY OF CARE, OUR QUALITY DEVICES

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